

# INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/FR2004/002654

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61M5/50 A61M5/315 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/35714 A (RESELLI, SERGIO; RIGHI, NARDINO) 20 August 1998 (1998-08-20) page 13, line 30 - page 15, line 27 figures 3,5 -----	1,3-8,10
A	WO 02/072182 A (GARTNER JODIE LEIGH; GLENORD PTY LTD (AU); INGRAM BRUCE WALLACE (A)) 19 September 2002 (2002-09-19) page 5, line 16 - page 6, line 6 page 6, line 29 - page 7 figures 1-5 -----	1,4
A	US 6 319 234 B1 (RIGHI NARDINO ET AL) 20 November 2001 (2001-11-20) column 6, line 12 - line 36 column 8, line 43 - line 46 figures 11-14 ----- -/-	1

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*C\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \*A\* document member of the same patent family

Date of the actual completion of the international search

20 May 2005

Date of mailing of the international search report

06/06/2005

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 653 667 A (FLOQUET NICOLE) 3 May 1991 (1991-05-03) page 2, line 17 - line 26 page 3, line 2 - line 10 figures 1BIS, 2, 4, 5 -----	1, 6, 12
A	FR 2 835 753 A (PLASTEF INVESTISSEMENTS) 15 August 2003 (2003-08-15) figure 3 -----	

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9835714	A	20-08-1998	IT SV970007 A1	12-08-1998
			IT SV970008 A1	12-08-1998
			AT 252925 T	15-11-2003
			AU 6719198 A	08-09-1998
			CA 2280716 A1	20-08-1998
			DE 69819352 D1	04-12-2003
			DE 69819352 T2	19-08-2004
			WO 9835714 A1	20-08-1998
			EP 1017436 A1	12-07-2000
WO 02072182	A	19-09-2002	WO 02072182 A1	19-09-2002
			CA 2440898 A1	19-09-2002
			CN 1505535 A	16-06-2004
			EP 1377331 A1	07-01-2004
			JP 2004528075 T	16-09-2004
			US 2004147875 A1	29-07-2004
US 6319234	B1	20-11-2001	AT 252925 T	15-11-2003
			AU 6719198 A	08-09-1998
			CA 2280716 A1	20-08-1998
			DE 69819352 D1	04-12-2003
			DE 69819352 T2	19-08-2004
			EP 1017436 A1	12-07-2000
FR 2653667	A	03-05-1991	FR 2653667 A1	03-05-1991
			FR 2654629 A2	24-05-1991
FR 2835753	A	15-08-2003	FR 2835753 A1	15-08-2003
			AU 2003226872 A1	04-09-2003
			EP 1474194 A1	10-11-2004
			WO 03068298 A1	21-08-2003

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

# PCT

Translation

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing **See Form PCT/ISA/210**  
(day/month/year) **(sheet 2)**

Applicant's or agent's file reference  
**H260360DI5MP**

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
**PCT/FR2004/002654**

International filing date (day/month/year)  
**18.10.2004**

Priority date (day/month/year)  
**22.10.2003**

International Patent Classification (IPC) or both national classification and IPC  
**A61M5/50, A61M5/315, A61M5/32**

Applicant  
**PLASTEF INVESTISSEMENTS**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/IEP

Authorized officer

Facsimile No.

Telephone No.

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Box No. 1

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
- ☐ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ in written format
- ☐ in computer readable form
- c. time of filing/furnishing
- ☐ contained in the international application as filed.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
<b>1. Statement</b>			
Novelty (N)	Claims	<u>2, 9, 11-14</u>	YES
	Claims	<u>1, 3-8, 10</u>	NO
Inventive step (IS)	Claims	_____	YES
	Claims	<u>1-14</u>	NO
Industrial applicability (IA)	Claims	<u>1-14</u>	YES
	Claims	_____	NO
<b>2. Citations and explanations:</b>			
<p>1      Reference is made to the following document:</p> <p style="margin-left: 40px;">D1:    WO 98/35714 A (RESTELLI, SERGIO; RIGHI, NARDINO) 20 August 1998</p> <p>2      INDEPENDENT CLAIM 1</p> <p>2.1   The present application fails to comply with the requirements of PCT Article 33(1) since the subject matter of claims 1, 3 and 10 does not meet the requirement of novelty defined in PCT Article 33(2). Document D1 describes (see, for example, page 13, line 30 to page 15, line 27, figures 3, 5 and 8) (the references between parentheses apply to this document):</p> <p style="margin-left: 40px;">Protected injection device, comprising a syringe with a syringe body (1), a needle (5), and a piston (3) which can be displaced in this body for an injection, and safety means that comprise a protective sleeve (14), the syringe body (1) and the protective sleeve (14) being able to slide relative</p>			

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

to one another between an injection configuration, in which the needle (5) protrudes from the protective sleeve (14) arranged around the syringe body, and a protection configuration, in which the needle (5) extends within said protective sleeve (14), the device comprising a trigger member (108) for triggering the change from the injection configuration (figure 3 without "protective cap (6)") to the protection configuration (figure 5) at the end of injection, the trigger member (108) being integral with the actuating head (8) of the piston (3), and in that it comprises an inhibitor member (21) able to occupy an inhibition position in which said inhibitor member (21) defines a first end-of-injection position of the piston (3) in which the trigger member (108) is unable to trigger the change from the injection configuration to the protection configuration and to be moved relative to this inhibition position in order to permit a second end-of-injection position of the piston in which the trigger member (108) is able to trigger the change from the injection configuration to the protection configuration, and in that, in its inhibition position, the inhibitor member (21) is connected to the piston (3) and integral with the movement of the latter and is able to cooperate in abutment with an element (7) of the device fixed relative to the syringe body (1) in order to define the first end-of-injection position, in that the inhibitor member (21) is able to be separated from the piston (3) or moved relative to the latter in order to allow the second end-of-

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

injection position to be obtained, and in that, in its inhibition position, the inhibitor member (21) is connected to the actuating head (8) of the piston (3).

Consequently, document D1 discloses all the features of claim 1 and in so doing deprives the latter's subject matter of any novelty, in accordance with PCT Article 33(2).

The same argument applies *mutatis mutandis* to the subject matter of independent claims **3 and 10**.

**3. DEPENDENT CLAIMS 2, 4-9 and 11**

The claims do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (PCT Article 33(2) and (3)). See for example:

**3.1 Novelty**

D1, page 13, line 30 - page 51, line 27, figures 3, 5 and 8, for claims 4-8;

**3.2 Inventive step**

The feature by which *the inhibitor member (34) passes through the head (12B) of the piston (12)* in claims **2, 9 and 11** is merely one of several obvious options that a person skilled in the art seeking to solve the stated problem might select, depending on each particular case, and without an inventive step



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being involved.

4 INDEPENDENT CLAIM 12

- 4.1 The solution proposed in claim 12 of the present application is not considered to be inventive (PCT Article 33(3)), the reasons being as follows:

The subject matter of independent claim 12 (the trigger member (52) is connected to the piston (12) and is able to be moved relative to the latter between a position permitting triggering ... and a position unable to permit triggering ...) refers to features representing merely one of several obvious options that a person skilled in the art seeking to solve the stated problem (namely that the change of the injection device at the end of injection in its protection configuration is not triggered systematically; see page 1, lines 33-36) might select, depending on each particular case, and without an inventive step being involved.

5 DEPENDENT CLAIMS 13 AND 14

- 5.1 Dependent claims 13 and 14 do not contain any features which, in combination with the features of any one of the claims to which they refer, meet the requirements of the PCT in respect of inventive step. This is because it would be obvious for a person skilled in the art to provide catch means on the trigger member and the piston in order to define their mutual positions as described in section 4.1 above.

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Box No. VIII      Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1.    Although claims 1, 3, 10 and 12 have been drafted as separate independent claims, it appears that they have the same subject matter and that they differ only by virtue of a variation in the definition of the subject matter for which protection is sought and in the terms used to define their features. Therefore, these claims are not concise and, as such, do not meet the requirements of PCT Article 6.